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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/678,082

10/06/2003

Jacobus M. Lemmens

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EXAMINER

SIMMONS, CHRIS E

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

06/03/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/678,082	<b>Applicant(s)</b> LEMMENS ET AL.	
	<b>Examiner</b> CHRIS E. SIMMONS	<b>Art Unit</b> 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 51-59 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 51-59 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>03/11/2009</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicants' arguments, filed 02/11/2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/11/2009 has been entered.

#### **Obviousness Rejection**

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Claims 51-59 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Pathak et al. (USP 6,113,944) in view of Benneker et al. (USP 5,874,447) and Chu (USP 4,675,188).

Applicant argues that the prior art does not teach or suggest the instant composition that has a pH within the range of 5 to 6. Applicant also submits that the prior art does not teach or suggest that pH is a parameter to be adjusted, much less adjusted to recite the range of 5 to 6. Applicant alleges that the reference to pH in the Chu reference is made in a completely different context from the presently recited pH. Accordingly, applicant asserts that it would not have been obvious to adjust the pH. The examiner contends that, firstly, the pH is a property of the composition and a prima facie case of either anticipation or obviousness can be established where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes. In this case, the prior art suggest a composition that is substantially identical to that which is claimed. Since the ingredients in the compositions disclosed in the prior art are the same as what is claimed, then the compositions would reasonably be considered to have similar pH values unless otherwise proven. Secondly, even if the pH would not be a characteristic of the substantially identical composition, the context of the pH as recited in the Chu reference is relevant in this case because it refers to the shape and size of the anhydrous dicalcium phosphate particles (instant claim 53) as being effected by pH. The size of anhydrous dicalcium phosphate particles is recognize as an important factor with regard to the compressibility of the tablets using dicalcium phosphate as a direct

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compression vehicle (col. 4, ll. 25-32). It has unexpectedly been found that the product of the Chu invention provided a surprising increase in compressibility even at low pressures. Accordingly, one of ordinary skill in the art making tablets containing dicalcium phosphate would find the disclosure of Chu relevant since it discloses how to optimize the compressibility of the composition to form tablets. Thirdly, the context in which the pH is referred to in the prior art is not required to be the same context as applicants recitation of pH because one of ordinary skill in the art can have a completely different reason or motivation than applicant's to make the claimed invention. As long as the prior art suggest the instant invention given a reasonable motivation, a prima facie case of obviousness is made.

Applicant argues that the reference only characterizes the pH of the aqueous composition from which dicalcium phosphate is made and not the final pharmaceutical product. Applicant's assertion that the reference only refers to the pH of solutions made during the process of making the dicalcium phosphate crystals is not found to be persuasive. Since the reference does disclose the pH during the process of making the dicalcium phosphate crystals, then the final product is reasonably considered to maintain a similar - if not the same - pH when mixed with the active ingredients to form the tablet. Further, as outlined above, the prior art suggest a composition that is substantially the same as the composition claimed. The characteristics are reasonably considered to be the same since the ingredients are the same unless shown otherwise. See MPEP Section 2112.01 [R-3]. Accordingly, the pH would reasonably considered to be the same.

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Applicant cites recent case law to support the notion that the current record does provide a prima facie case of obviousness because the rejection does not provide a reason one of ordinary skill in the art would want to modify the pH of the claimed composition. The Board explained that "where the parameter optimized was not recognized in the prior art as one that would affect the results," the doctrine of routine optimization does not apply. Moreover, where there is no evidence of record that "would support the conclusion that those skilled in the art would have considered it obvious to 'optimize' [the parameter at issue]...to the level recited in the claims," a finding of obviousness is improper. It is submitted that the facts of the current record, unlike those of the cited case law, provide a record where the parameter is recognized in the prior art to affect a result, i.e., the Chu reference cited by the examiner provides that pH affects the size and shape of the dicalcium phosphate crystals and provides an adjustable parameter that can be used to ultimately optimize the compressibility of tablets containing same. Accordingly, the case law does not support applicant's position in this case.

### ***Conclusion***

No claims are allowable at this time.

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***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRIS E. SIMMONS whose telephone number is (571)272-9065. The examiner can normally be reached on Monday - Friday from 7:30 - 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. E. S./  
Examiner, Art Unit 1612  
/Gollamudi S Kishore/  
Primary Examiner, Art Unit 1612

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